

## **REMARKS**

Applicant intends this response to be a complete response to the Examiner's 11 June 2007 Final Office Action. Applicant has labeled the paragraphs in his response to correspond to the paragraph labeling in the Office Action for the convenience of the Examiner.

## **DETAILED ACTION**

## ***Claim Objections***

**The Examiner states as follows:**

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

The preliminary amendment filed 21 October 2005 improperly included two claims numbered 59 and two claims numbered 71.

Misnumbered claims 59 (second occurrence) - 71 (first occurrence) have been renumbered 60 - 72 and misnumbered claims 71 (second occurrence) - 79 have been renumbered 73 - 81. Applicant is requested to review the claims and update the dependencies accordingly to account for this correction.

Applicants' attorney apologizes for the repeated claim. In cutting and pasting, a first part of the counters was not copied losing the incrementing features and the line numbering feature. Applicants have corrected the claim numbering in accord with the Examiner and thank the Examiner for his assistance.

**The Examiner states as follows:**

2. **Claim 69** is objected to because of the following informalities: it appears that the phrase "two transitions section" should read "two transition sections". Appropriate correction is required.

Applicants have amended claim 69 as the Examiner kindly suggests, and request withdrawal of this claims objection.

### ***Claim Rejections - 35 USC § 112***

4,      **Claims 49, 50, 52 - 54, 60, 62, 64 - 66, and 69 - 81** stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**The Examiner contends as follows:**

With regard to claims 49, 60, and 73, the claims do not appear to set forth a further limitation, since all radiation (as set forth in the base claims) would necessarily either be of a single wavelength (or frequency) or a plurality of wavelengths (or frequencies). With regard to claims 50, 62, and 75, since the phrase "above about 1120 nm" does not set forth an upper limit to the range, the scope of the claim is not clearly set forth.

Applicants have amended claims 49, 60 and 73 to add the limitation "from about 1120 nm to about 1130 nm", support for this can be found in the experimental section where 1120 and 1130 were used as examples within the range of 760 to 2500 nm. Applicants, therefore, respectfully requests withdrawal of these section 112, 2<sup>nd</sup> paragraph rejections.

The Examiner contends as follows:

With regard to claims 52 - 54, 64 - 66, and 77 - 79, it is noted that while the claim sets forth a limitation of one element of a Markush group (exogenous substance), it is not limiting to any other members of the group. It appears that in these claims Applicant should first establish that the selected blood component is an exogenous substance, and then require that the exogenous substance has the features as set forth in the various claims..

Applicants have amended claims 51 and 52, 63 and 64, and 76 and 77. In claims 51, 63, and 76, Applicants have removed exogenous substance. In claims 52, 64 and 77, Applicants have added that the blood component is an exogenous substance selected . . . Applicants believe that these amendments overcome these 112, 2<sup>nd</sup> rejections, and respectfully request withdrawal of same.

The Examiner contends as follows:

With regard to claim 69, the phrases "the radiation outlet" and "the response inlet" lack antecedent basis.

Applicants have amended the claims to read a radiation outlet and a response inlet, and respectfully request withdrawal of these section 112, 2<sup>nd</sup> paragraph rejections.

Applicants hereby assert that the above amendments did not result in the narrowing any claim, but were simply to remove inconsistencies in the claims structures.

***Claim Rejections - 35 USC § 101***

6. **Claims 69 - 81** stand rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The Examiner states as follows:

The claims improperly include a portion of a living being ("surface of a tissue over a big vein associated with an underside of the patient's tongue") as part of the claimed subject matter. It appears that the phrase "are proximate or in contact with" should read "are adapted to be proximate or in contact with" to avoid positively claiming the connection with the living being.

Applicants thank the Examiner for his suggestions and have modified the claims accordingly. It was not the intent of the Applicants to claim the patient tongue as an element of the claim, but to ensure that the method was direct at viewing the blood in vessels located on the underside of a patient's tongue. Because Applicants have made the suggested correction, Applicants respectfully request withdrawal of these 101 rejection

***Claim Rejections - 35 USC § 102***

8. **Claims 45 - 67** stand rejected under 35 U.S.C. 102(b) as being anticipated by Hatschek.

The Examiner states as follows:

Hatschek teaches an optical measurement system (Figure 4; column 6 - 8) suitable for determination of oxygen saturation from the underside of a subject's tongue (column 11, lines 41 - 64). It is inherent that at least some of the measurement light would irradiate a big vein of the subject's tongue and that the detecting step would be performed in the presence of a static (earth's) magnetic field.

Hatschek is directed to measuring oxygenation of blood through oxyhemoglobin or the ratio of oxyhemoglobin to total hemoglobin as is true for the present invention. However the method is substantially different. Hatschek is directed at measuring blood in the capillaries in the dermis near the epidermal boundary. Hatschek also uses heating to improve oxygenation measurement, where heating is affected by ultrasound, while measurements are made optically.

Clearly, the optical regions are similar as they represent the hemoglobin absorption regions of the electromagnetic spectrum. However, the present invention does not look at the dermis, but looks directly into a large vessel on the underside of the tongue. No heating is needed at the probe is positioned directly on the exterior of the large vessels so that the data obtained is from blood in the vessel and not blood in a dermal layer where blood flow may be variable.

Hatschek does not teach a probe sized so that the tip is proximate to or in contact with a big vein associated with an underside of a patient's tongue. The radiation outlet and the response inlet are both located in the tip, both being proximate or in contact with the surface of the big vein. Not only does Hatschek not teach such an arrangement, the Hatschek probes are not conductive to such an arrangement. The Hatschek probes of Figures 1-3, and 6-10 require an ultrasound transmitter to heat the tissue; and even the Hatschek probe of Figure 11 requires a motor and a reflective system for irradiating a large skin area to improve the detectable response.

Because Hatschek does not disclose these feature, Hatschek cannot anticipate these claims. Applicants, therefore, respectfully request withdrawal of this section 102(b) rejection.

*Claim Rejections - 35 USC § 103*

10. **Claim 68** stands rejected under 35 U.S.C. 103(a) as being unpatentable over Hatschek as applied to claim 57 above, and further in view of Takeuchi et al.

The Examiner states as follows:

Hatschek teaches all of the features of the claimed invention except for a device for generating a static magnetic field. Takeuchi et al. (Figure 1 and the description thereof) teach that a device for generating a static magnetic filed is required to perform magnetic resonance measurements in coordination with optical measurements of a subject. It would have been obvious to one of ordinary skill in the art at the time of the invention to implement Hastchek with a device for generating a static magnetic field, as taught by Takeuchi et al., since this allows magnetic resonance measurements to be performed in addition to to the optical measurements.

Applicants reassert their argument relating to Hatschek here, and note that Hatschek does not disclose, teach or suggest that the probe tip be adapted to be proximate to or in contact with a large vein on the underside of the tongue. As the probe tip include a radiation outlet and a response inlet, both are simultaneously proximate to or in contact with the large vein. There simply is not teaching or suggestion to change the Hatschek probe, which either require a separate ultrasound component as in the Hatschek probes of Figures 1-3 and 6-10 or a large area light component as in the Hatschek probe of Figure 11, into a probe including a tip having radiation outlet and a response inlet that can be positioned proximate to or in contact with a large vein on the underside of the tongue. The addition of a magnetic field as taught by Takeuchi et al. does nothing to alleviate the deficiencies of Hatschek.

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Because Hatschek nor a combination of Hatschek and Takeuchi et al. disclose, teach or even suggest the apparatus of claims 68, Hatschek nor a combination of Hatschek and Takeuchi et al. cannot render the present invention obvious.

Applicants are submitting herewith a supplemental IDS, for the Examiner's consideration.

*Conclusion*

The Examiner states as follows:

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Nielsen teach that an oximeter arrangement, such as that of Hatschek, can obtain measurements of carboxyhemoglobin by including an additional wavelength sensitive to carboxyhemoglobin in the measurement arrangement. Hoeft teaches a measurement arrangement for measuring oxygen saturation and cardiac output with use of indicator dyes such as indocyanine green. Stavridi et al. teach an optical glucose measurement device that can perform measurements from the base of a subject's tongue. Caro teaches optical measurement of analytes, including cholesterol, wherein measurements may be obtained from a subject's tongue. The prior art does not teach or suggest a measurement arrangement including a middle section interposed between two transition sections extending downwardly from each of two side sections, the middle section adapted to be proximate to or in contact with an underside of a patient's tongue that includes an emitter and receiver, in combination with the other claimed elements, for determining a concentration of a blood component and/or value of a parameter of the blood.

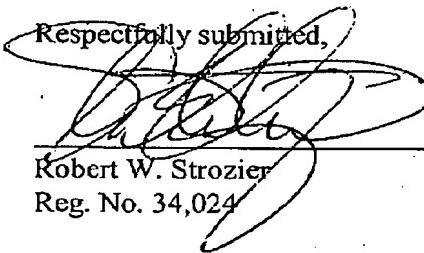
Applicants acknowledge these statements.

If it would be of assistance in resolving any issues in this application, the Examiner is kindly invited to contact applicant's attorney Robert W. Strozier at 713.977.7000.

**The Commissioner is authorized to credit or debit deposit account number 501518 if required for this response.**

Date: September 27, 2007

Respectfully submitted,

  
Robert W. Strozier  
Reg. No. 34,024

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